UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,393	03/19/2001	Hiroyuki Sugiuchi	2139.22	2399

5514 7590 05/16/2002

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
CHAUDHRY, MAHREEN F	

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,393	Applicant(s) KUMAMOTO, HIROYUKI SUGIUCHI	
	Examiner Mahreen Chaudhry	Art Unit 1627	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,14,15 and 17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,14,15 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-9, 12, 14, 15 and 16-27 in Paper No. 7 is acknowledged. Claims 10, 11, 13 and 16 corresponding to group II are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and have been cancelled.

This restriction not having been specifically traversed has been treated as an election without traverse.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9, 12, 14-15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear with regard to the phrase "cholesterol esterase and cholesterol oxidase or cholesterol dehydrogenase." It is unclear if this phrase is intended to refer the CH enzymes as a combination of cholesterol esterase and cholesterol esterase or cholesterol dehydrogenase alone or whether the phrase is intended to refer to the CH enzymes as a combination of cholesterol esterase and cholesterol oxidase or the combination of cholesterol esterase and cholesterol dehydrogenase.

Claim 1 recites the limitation "the hydrogen peroxide" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the first reaction" in line 4 of the claim, the limitation "the hydrogen peroxide" in line 10 of the claim and the limitation "the second reaction" in line 16 of the claim. There is insufficient basis for each of these limitations in the claim.

Claim 6 recites the limitation "the first reaction" in line 11 of the claim, the limitation "the second reaction" in line 17 and the limitation "the hydrogen peroxide" in line 18 of the claim. There is insufficient basis for each of these limitations in the claim.

Claim 17 is unclear with regard to the phrase "a reagent for determining LDL cholesterol comprising CH enzymes and a reagent enabling the CH enzymes to act only on LDL cholesterol." It is unclear if the claim is directed to a single reagent comprising CH enzymes and a reagent enabling the CH enzymes to act only on CH enzymes or if the claim is directed to a reagent comprising CH enzymes and a reagent which enables the CH enzymes to act only on LDL cholesterol.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,333,166 B1 issued to Nakamura et al. Nakamura et al. discloses a method for quantitatively determining LDL cholesterol including the addition of a surfactant which accelerates the reaction of HDL and VLDL and that allows LDL to be measured fractionally by appropriate selection of a point of measurement (column 2, lines 35-48). Nakamura et al. disclose that the surfactants may be polyoxyethylene ether and that the surfactants may be used singly or in combination (column 3, lines 31-44). Nakamura et al. discloses that the specific amount of LDL reaction is determined after termination of the reaction in cholesterols other than in LDL (column 4, lines 19-26). Nakamura et al. further disclose that the method of measuring LDL cholesterol includes a method employing a combination of cholesterol esterase and cholesterol oxidase as the enzyme reagent (column 4, lines 5-11). Nakamura et al. additionally disclose that the method may include peroxidase and a chromogen for detection of hydrogen peroxide (column 4, lines 5-18). Nakamura et al. teaches a method for quantitatively determining the amount of cholesterol by adding to the sample a surfactant and a cholesterol assaying enzyme reagent followed by determining the amount of cholesterol in the LDL after acceleration of the reaction of enzyme reagent with HDL and VLDL (column 6, lines 20+).

6. Claims 1 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,925,534 issued to Miki et al. Miki et al. disclose a method for determining LDL cholesterol by contacting a sample with a reagent solution comprising cholesterol esterase and cholesterol oxidase and determining the amount of hydrogen peroxide produced (column 3, lines 51-59).

Miko et al. further disclose that the amount of cholesterol is measured in the presence of a polyanion and an amphoteric surfactant so as to carry out the reaction of lipoproteins other than LDL first followed by specifically measuring the LDL cholesterol (column 4, lines 18-33).

7. Claims 1 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugiuchi et al. Sugiuchi et al. disclose a method for the measurement of low density lipoprotein cholesterol using a non-ionic surfactant and a polyoxyethylene-polyoxypropylene block copolyether. Sugiuchi et al. disclose that the copolyether reduced the reactivity of lipoprotein cholesterol and allows for the selective determination of LDL cholesterol (abstract). Sugiuchi et al. disclose that LDL cholesterol is measured using a reagent which contains the non-ionic surfactant, cholesterol oxidase, cholesterol esterase and polyoxyethylene-polyoxypropylene block copolyether (p 523).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-4, 5-9, 12, 14-15, 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiuchi et al. in view of U.S. Patent 5,773,304 issued to Hino et al. The applicability of Sugiuchi et al. to the instant invention has been discussed above. Sugiuchi et al. teach that the reactivities of cholesterol in lipoprotein fractions other than LDL must be inhibited in order to selectively determine LDL cholesterol (p 526). Sugiuchi et al. teach that the

reactivity of HDL may be inhibited by the inclusion of polyoxyethylene-polyoxypropylene polymer and that the reactivity of cholesterol in VLDL and chylomicron may be suppressed by a non-ionic surfactant; Sugiuchi et al. specifically exemplifies α-cyclodextrin sulfate. Sugiuchi et al. does not disclose that the non-ionic surfactant utilized to inhibit cholesterol reactivity may be a polyoxyethylene derivative. However, Hino et al. teach that surfactants which inhibit the reaction between enzymes and lipoprotein cholesterols include polyoxyethylene alkyl ethers and polyoxyethylene-polyoxypropylene condensation products (column 2, lines 60+). Hino et al. further teach that the surfactants may be utilized singly or in combination (column 3, lines 16-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to have specifically measured LDL cholesterol by inhibiting the reactivity of cholesterol in other lipoproteins using a polyoxyethylene-polyoxypropylene copolymer, as specifically taught by Sugiuchi et al., and to have replaced the non-ionic surfactant, α-cyclodextrin sulfate, with another appropriate non-ionic surfactant such as a polyoxyethylene derivative as taught by Hino et al. A motivation for utilizing a polyoxyethylene derivative in combination with the polymer taught by Sugiuchi et al. is provided by Hino et al. who teaches that polyoxyethylene derivatives inhibits the interaction between enzymes and lipoprotein cholesterol and that polyoxyethylene derivatives, including polyoxyethylene-polyoxypropylene condensation products and polyoxyethylene alkyl ethers, may be used in combination.

Sugiuchi et al. is directed to a method for the specific determination of LDL cholesterol and does not expressly disclose a method for specifically determining LDL cholesterol and HDL cholesterol. Hino et al., however, disclose a method for specifically determining HDL cholesterol. Hino et al. disclose that the specific determination of HDL cholesterol is carried out

by introducing a reagent which results in the formation of a complex with lipoproteins other than HDL (column 2, lines 37+). Hino et al. further disclose that such substances include dextran sulfate and phosphotungstic acid (column 2, lines 40-45). Hino et al. additionally teach that cholesterol esterase and cholesterol oxidase may be combined and used as enzyme reagents in the measurement of cholesterol and hydrogen peroxide may determined (column 3, lines 33-46). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the method taught by Hino et al. for the specific determination of HDL cholesterol and to have then specifically determined LDL cholesterol by utilizing a non-ionic surfactant and polyoxyethylene-polyoxypropylene copolymer as taught by Sugiuchi et al. Neither Sugiuchi et al. nor Hino et al. specifically disclose a kit for determining HDL cholesterol and LDL cholesterol. However it would certainly have been obvious to one having ordinary skill in the art at the time of the invention to have simply packaged the components taught by Hino et al. and Sugiuchi et al. for the measurement of cholesterol together in the form of a kit.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,925,534 issued to Miki et al. discloses a method for determining the amount of cholesterol in low density lipoproteins by conducting the reaction in the presence of a polyanion and an amphoteric surfactant.

U.S. Patent 5,879,901 issued to Futatsugi et al. discloses a method for specifically measuring LDL cholesterol including a surfactant such as polyoxyethylene alkylphenylether.

U.S. Patent 5,804,450 issued to Karl discloses a method and reagent for the specific determination of LDL cholesterol by the addition of LDL aggregating agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
May 13, 2002

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200